

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Effects of non-invasive vagus nerve stimulation and vestibular rehabilitation on dizziness, and postural control in adults with vestibular migraine

Protocol summary

Study aim

Effects of non-invasive vagus nerve stimulation and vestibular rehabilitation on dizziness, and postural control in adults with vestibular migraine

Design

Randomized, clinical trial with a parallel group design on 28 patients. Randomization was carried out with Random Allocation Software.

Settings and conduct

Setting: School of Rehabilitation, TUMS. Recruitment of patients with vestibular migraine based on inclusion criteria, random allocation, intervention based on the group description (VR/nVNS/VR+nVNS/VR+shamVNS) for 4 weeks, and assessment and comparison of balance system (DHI, VSS, vHIT, and static postural control) outcomes before and after interventions.

Participants/Inclusion and exclusion criteria

Patients diagnosed with Vestibular Migraine (diagnosed by a neurologist and based on ICDH-3 guidelines)

Intervention groups

1)VR group: receiving vestibular rehabilitation every day for four weeks 2) nVNS group: receiving nVNS (12 sessions, three times a week for 4 weeks, each stimulation session for 30 minutes) 3) VR+nVNS group: receiving vestibular rehabilitation and nVNS 4) VR+ShamVNS group: received vestibular rehabilitation and sham nVNS

Main outcome variables

The overall score and subcategories of the Dizziness Handicap Inventory Questionnaire, the overall score of the vertigo Symptoms Scale Questionnaire (short version), the frequency of vertigo/dizziness, video head Impulse Test, static posturography.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160131026279N5**
Registration date: **2023-06-25, 1402/04/04**
Registration timing: **registered_while_recruiting**

Last update: **2023-06-25, 1402/04/04**

Update count: **0**

Registration date

2023-06-25, 1402/04/04

Registrant information

Name

Mansoureh Adel Ghahraman

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7753 4364

Email address

madel@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-21, 1402/03/31

Expected recruitment end date

2026-01-19, 1404/10/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of non-invasive vagus nerve stimulation and

vestibular rehabilitation on dizziness, and postural control in adults with vestibular migraine

Public title

The effect of rehabilitation and non-invasive vagus nerve stimulation on the treatment of vestibular migraine

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age range of 18-50 years, people with vestibular migraine (diagnosed by a neurologist and based on ICDH-3 guidelines) no change in preventive medications during the last 2 months and during the study, no use of suppressive medications Compensating the vestibular system with the opinion of an expert doctor related to the thesis, no history of other vestibular disorders, Meniere's disease, ear surgery, intracranial surgery, posterior circulation stroke, epilepsy, severe cardiovascular disease, severe carotid artery disease, Previous carotid artery surgery, or implanted electrical devices. no visual and motor deficit, no history of previous vestibular rehabilitation program, sufficient visual acuity to see the target point in the vHIT test.

Exclusion criteria:

Use of drugs that suppress vestibular system compensation, suffering from neck pain and limited range of motion of the neck, alcohol and drug use, history of orthopedic problems in the last 6 months obvious deformity of the lower limbs such as scoliosis and kyphosis based on the observation of a physiotherapist history of rheumatic or metabolic diseases based on individual report.

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **28**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Individual random assignment to four equal groups with block randomization method using blocks of size 4; Randomization and random sequential allocation: done with Random Allocation Software;

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of School of Nursing and Midwifery & Rehabilitation - Tehran University of Medical

Street address

Enghelab Ave.

City

Tehran

Province

Tehran

Postal code

1148956111

Approval date

2023-02-01, 1401/11/12

Ethics committee reference number

IR.TUMS.FNM.REC.1401.160

Health conditions studied

1

Description of health condition studied

vestibular migraine

ICD-10 code

G43

ICD-10 code description

Migraine

Primary outcomes

1

Description

Dizziness Handicap Inventory score

Timepoint

Before and after intervention

Method of measurement

Dizziness Handicap Inventory

2

Description

The total score of the vertigo symptom scale

Timepoint

Before and after intervention

Method of measurement

the vertigo symptom scale

3

Description

Frequency of vertigo/dizziness

Timepoint

Before and after intervention

Method of measurement

vertigo/Dizziness frequency form with numbering 0-6

4**Description**

Vestibulo-ocular reflex gain

Timepoint

Before and after intervention

Method of measurement

video head impulse test (vHIT)

5**Description**

Frequency of covert and overt saccades

Timepoint

Before and after intervention

Method of measurement

video head impulse test (vHIT)

6**Description**

Displacement of center of pressure in both anterior-posterior and medial-lateral directions

Timepoint

Before and after intervention

Method of measurement

Static posturography on force-plate and calculation with formula

7**Description**

velocity of displacement of center of pressure in both anterior-posterior and medial-lateral directions

Timepoint

Before and after intervention

Method of measurement

Static posturography on force-plate and calculation with formula

8**Description**

Overall average velocity

Timepoint

Before and after intervention

Method of measurement

Static posturography on force-plate and calculation with formula

9**Description**

The area of displacement of the center of pressure

Timepoint

Before and after intervention

Method of measurement

Static posturography on force-plate and calculation with formula

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Intervention group 1 (VR): receiving vestibular rehabilitation program (exercises including seven VOR exercises, eight static VSR exercises and five dynamic VSR exercises), every day, 4 weeks.

Category

Rehabilitation

2**Description**

Intervention group: Intervention group 2 (nVNS): receiving non-invasive vagus nerve stimulation, each stimulation session for 30 minutes (frequency 1 Hz, duration 0.2 milliseconds and the intensity of stimulation is the strongest sensation that patients can tolerate without pain), three times a week, 12 sessions, 4 weeks

Category

Rehabilitation

3**Description**

Intervention group: Intervention group 3 (VR+nVNS): receiving vestibular rehabilitation exercises along with non-invasive vagus nerve stimulation, 4 weeks

Category

Rehabilitation

4**Description**

Intervention group: Intervention group 4 (VR+sham nVNS): receiving vestibular rehabilitation exercises along with non-invasive vagus nerve stimulation as a sham, 4 weeks

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

The Neurology Clinic of Sina Hospital, Tehran, and Audiology clinic, School of Rehabilitation, Tehra

Full name of responsible person

Mansoureh Adel Ghahraman

Street address

Enghelab Ave.

City

Tehran

Province

Tehran

Postal code
1148956111
Phone
+98 21 7753 0636
Email
madel@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Hamid Dalvand
Street address
School of Rehabilitation, Pich-e-hemiran, Enghelab Ave.
City
Tehran
Province
Tehran
Postal code
1148956111
Phone
+98 21 7753 4364
Email
rehabilitation@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mansoureh Adel Ghahraman
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Audiology
Street address

Enghelab Ave.
City
Tehran
Province
Tehran
Postal code
1148956111
Phone
+98 21 7753 4364
Fax
+98 21 7753 4133
Email
madel@tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mansoureh Adel Ghahraman
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Audiology
Street address
Enghelab Ave.
City
Tehran
Province
Tehran
Postal code
1148956111
Phone
+98 21 7753 4364
Fax
+98 21 7753 4133
Email
madel@tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mansoureh Adel Ghahraman
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Audiology
Street address
Enghelab Ave.
City
Tehran
Province
Tehran

Postal code

1148956111

Phone

+98 21 7753 4364

Fax

+98 21 7753 4133

Email

madel@tums.ac.ir

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Reporting as a PhD dissertation and papers

When the data will become available and for how long

2025 and after

To whom data/document is available

All people

Under which criteria data/document could be used

Dissertation: In accordance with Tehran University of Medical Sciences copyright Paper: In accordance with the journal's policies to access the published paper

From where data/document is obtainable

Dissertation: The library of the School of Rehabilitation, TUMS Papers: Databases

What processes are involved for a request to access data/document

For the dissertation, studying in the library For papers depends on the journal's policy.

Comments